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December 30, 1986

*Handwritten initials: JH*

Mr. Ronald Wilson  
Office of the Associate Commissioner  
for Health Affairs (HFY-20)  
Room 11-46  
Food and Drug Administration  
5600 Fishers Lane  
Rockville, MD 20857

RE: Tegison  
FDA Docket # 86E-0491

Dear Mr. Wilson:

Transmitted herewith is a copy of the application for Patent Extension of U.S. Patent No. 4,215,215, issued July 29, 1980. The application was filed on November 21, 1986 under Title II of Public Law 98-417, the Drug Price Competition and Patent Term Restoration Act of 1984.

The patent claims a product that was subject to regulatory review under the Federal Food, Drug and Cosmetic Act. Subject to final review, the subject patent is considered to be eligible for patent term restoration. Thus, a determination of the applicable regulatory review period is necessary. Accordingly, notice and a copy of the application are provided pursuant to 35 USC 156(d)(2)(A).

*Handwritten signature: C. E. Van Horn*

Charles E. Van Horn  
Director, Group 120  
U.S. Patent and Trademark Office

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